

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Docket No. FDA-2008-N-0312

Agency Information Collection Activities; Submission for Office of Management and Budget

Review; Comment Request; Extralabel Drug Use in Animals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to <a href="mailto:oira\_submission@omb.eop.gov">oira\_submission@omb.eop.gov</a>. All comments should be identified with the OMB control number 0910-0325. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Road; COLE-14526, Silver Spring, MD 20993-0002 PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Extralabel Drug Use in Animals--21 CFR 530 (OMB Control Number-0910-0325)--(Extension)

The Animal Medicinal Drug Use Clarification Act of 1994 allows a veterinarian to prescribe the extralabel use of approved new animal drugs. Also, it permits FDA, if it finds that there is a reasonable probability that the extralabel use of an animal drug may present a risk to the public health, to establish a safe level for a residue from the extralabel use of the drug, and to require the development of an analytical method for the detection of residues above that established safe level. Although to date we have not established a safe level for a residue from the extralabel use of any new animal drug and, therefore, have not required the development of analytical methodology, we believe that there may be instances when analytical methodology will be required. We are, therefore, estimating the reporting burden based on two methods being required annually. The requirement to establish an analytical method may be fulfilled by any interested person. We believe that the sponsor of the drug will be willing to develop the method in most cases. Alternatively, FDA, the sponsor, and perhaps a third party may cooperatively arrange for method development. The respondents may be sponsors of new animal drugs, State, or Federal and/or State Agencies, academia, or individuals.

In the <u>Federal Register</u> of November 4, 2014 (79 FR 65408), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

21 CFR Section	No. of	No. of	Total Annual	Average	Total Hours
	Respondents	Responses per	Responses	Burden per	
	_	Respondent	_	Response	
530.22(b)	2	1	2	4,160	8,320

<sup>&</sup>lt;sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: January 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

4164-01-P

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